DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

REGULATORY LETTER

JUN 15 1987

Mr. Joseph Harmon, President
Coty Division of Pfizer
235 - East 42nd Street
New York, New York 10017

Re: 87-HFN-312-27

Dear Mr. Harmon:

This letter is in reference to a representative selection of your skin treatment products; namely 1) "overnight success CELLULAR REPLACEMENT CREAM" and 2) "COTY overnight success INSTANT UNDER EYE FIRMER" and any other of your products that bear similar or related labeling statements. A review of the labeling reveals what the Food and Drug Administration believes are drug claims.

The products are described in their labeling which includes but is not limited to packaging, package inserts, containers, and accompanying promotional brochures. The labeling bears statements which include but are not limited to the following:

A package insert bears general labeling statements as follows: "... a remarkable advance in face treatment technology ... so effective it virtually reverses the aging look ... Phases in ... younger looking skin. ... Clinical tests prove it. After just 3 nights use, 98% of women showed measurable improvements. ..."

In addition, other labeling for specific products as follows:

> 1) "overnight success CELLULAR REPLACEMENT CREAM": "... diminish the aging look ... improvement begins overnight ... you may feel a slight tingling sensation as the formula goes to work."
>
> 2) "COTY overnight success INSTANT UNDER EYE FIRMER": "... So effective, within minutes eyes look younger. Reduces fine, dry lines and crepiness ... clinical tests prove it. ..."

In summary, the aforementioned claims represent and suggest that the articles are intended to affect the structure and function of the human body, and that the products are adequate and effective for such uses as reversing the aging look, cellular replacement, and other claims. Because of such claims, the products are regarded as drugs as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act (Act). Also, we are unaware of any substantial scientific evidence that demonstrates the safety and effectiveness of these articles for their intended uses, nor are we aware that these drugs are generally recognized as safe and

effective for their intended uses. Therefore, the products are new drugs within the meaning of section 201(p) of the Act.

In conclusion, we regard the Coty/Pfizer products to be in serious violation of the act as follows:

SECTION	BRIEF DESCRIPTION
505(a)	The articles 1) "overnight success CELLULAR REPLACEMENT CREAM" and 2) "COTY overnight success INSTANT UNDER EYE FIRMER" are new drugs within the meaning of 201(p) of the Act, and no approval of an application filed pursuant to Section 505(b) is effective for such drugs.
502(f)(1)	The articles are misbranded in that their labeling fails to bear adequate directions for use.
502(e)	The article "Coty overnight success INSTANT UNDER EYE FIRMER" is further misbranded in that its immediate container label fails to declare the active ingredient(s).
502(o)	The articles are further misbranded because they are not included in a list required by Section 510(j) and 21 CFR 207.

The Agency has not reviewed your entire product line; therefore, the violative products described above are not all inclusive. It is your responsibility to ensure that all of your products are the subject of approved new drug applications as appropriate and that the products are properly labeled for their intended uses.

We request that you take prompt action to correct these violations. If such action is not taken, the Food and Drug Administration is prepared to take appropriate regulatory sanctions such as seizure or injunction (21 U.S.C. 332 and 334). Please advise us within ten (10) days as to the specific actions you have taken or intend to take, including measures to prevent the recurrence of the violations, and an explanation of any potential delays in correcting the violations that may occur. Your reply should be directed to Roma Jeanne Krause, OTC Compliance Branch, (HFN-312) Phone 301-295-8065.

Sincerely yours,

Daniel L. Michels, Director
Office of Compliance
Center for Drugs and Biologics

cc:
HFR-21
HFR-2100
HFR-2140
HFC-210
HFI-35 (Wade White or Ben Carney)
HFI-20 (Stone)
HFI-20 (Woodworth)
HFI-21 (Corwin)
HFN-300 (Harris)
HFN-310 (Fay)
HFN-10 (Hooton)
HFA-224
HFN-315 (BYER)
HFN-312-DDLC
HFN-312 R/F
HFN-310 R/F
INIT:RHeller:6/11/87
RJKrause:rlf:5/26/87:6/11/87
2950F